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May 7, 2024

VIA CM/ECF

Honorable Jennifer L. Hall
J. Caleb Boggs Federal Building
844 N. King Street, Room 6312
Wilmington, DE 19801-3555

Re: Nippon Shinyaku Co. v. Sarepta Therapeutics, Inc., C.A. No. 21-1015-JLH

Dear Judge Hall:

Pursuant to the Court's May 7, 2024 Oral Order (D.I. 566), we write on behalf of Nippon Shinyaku Co., Ltd. ("Nippon Shinyaku") and NS Pharma (collectively, "NS") to advise the Court regarding NS's position on the claim construction and trial scheduling issues discussed at the Pretrial Conference.

With trial just days away, Sarepta Therapeutics, Inc. ("Sarepta") and the University of Western Australia ("UWA") seek the reversal of Judge Williams's construction of "base sequence." This would needlessly derail trial regarding the Sarepta/UWA patent-in-suit. Moreover, as set forth in Judge Williams's opinion, Sarepta's construction is legally incorrect for several reasons including that it renders terms superfluous, fails to recognize that "comprising" means "including," fails to give different claim terms different meanings ("antisense oligonucleotide" v. "base sequence"), fails to recognize that "a" means "one or more," and excludes certain preferred embodiments while reading other embodiments into the claims.

NS therefore respectfully requests that the Court preserve the meaning of "base sequence" that Judge Williams adopted, and, at most, clarify it using plain language (Section II below) and proceed with trial as scheduled.

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I. Leaving Judge Williams’s Construction Undisturbed

NS’s position is that this Court should not disturb Judge Williams’s construction of U.S. Patent 9,994,851 (the “’851 Patent”)—the sole remaining Sarepta/UWA patent-in-suit. Judge Williams correctly held that “a base sequence” should be construed to have its plain and ordinary meaning, which is “any sequence of bases that is part of the antisense oligonucleotide.” *See* D.I. 249. Because both sides’ experts explicitly addressed this construction, if the Court does not disturb it, the trial can proceed as scheduled.

II. Clarifying Judge Williams’s Construction of “Base Sequence”

If the Court believes that the particular words “any sequence of bases that is part of the antisense oligonucleotide” should be simplified to better convey the meaning Judge Williams adopted to the jury, NS proposes that the Court clarify that the recited “base sequence” is simply a “**portion**” of the claimed “antisense oligonucleotide”:

1. An antisense oligonucleotide of 20 to 31 bases comprising a **portion** that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the target region is within annealing site H53A(+23+47) and annealing site H53A(+39+69), wherein the **portion** comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195), in which uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, and wherein the antisense oligonucleotide induces exon 53 skipping; or a pharmaceutically acceptable salt thereof.

This clarification directly mirrors the language Judge Williams himself used to describe the dispute he resolved. D.I. 248 at 7 (“The crux of the parties’ dispute is whether ‘a base sequence’ can be **a portion of the claimed oligonucleotide**, or whether it must include all bases of the ‘antisense oligonucleotide,’ i.e., each antisense oligonucleotide has a single base sequence.”). And by using simple, well-known language, the jury would immediately understand that claimed antisense oligonucleotides need only comprise a “portion” that is “100% complementary.”

Because this clarification applies the same meaning Judge Williams adopted, both sides’ experts have provided opinions applying it, and NS understands that the trial could proceed as scheduled.

III. Clarifying the Preamble Language “Antisense”

If the Court preserves the meaning of “base sequence” adopted by Judge Williams (either Section I or II, above), yet additionally believes that the preamble language “An antisense oligonucleotide” is limiting (as Sarepta’s expert, Dr. Dowdy, asserted in expert reports and Sarepta and UWA argued in their motion *in limine*), then NS respectfully requests that the Court construe that term to reflect the intrinsic evidence, rather than adopting Dr. Dowdy’s

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“highly complementary” characterization. The specification disclosure upon which Dr. Dowdy relies explains:

An antisense molecule is specifically hybridisable when binding of the compound to the target DNA or RNA molecule interferes with the normal function of the target DNA or RNA to cause a loss of utility, and there is a sufficient degree of complementarity to avoid non-specific binding of the antisense compound to non-target sequences under conditions in which specific binding is desired,

’851 Patent at 25:28-38. Accordingly, a more faithful construction of “An antisense oligonucleotide” (if limiting), would be “an oligonucleotide that binds to a pre-mRNA target with sufficient complementarity to avoid nonspecific binding.”

Although NS disagrees that this preamble language is limiting, both sides’ experts have provided opinions that assume that language limits the claims. Thus, if the Court adopts either Dr. Dowdy’s “highly complementary” language or the alternative NS identifies herein, NS understands that the trial can proceed as scheduled.

IV. Reversing Judge Williams’s Construction of “Base Sequence”

NS is not in a position to proceed to trial regarding the ’851 Patent if the Court wholesale reverses Judge Williams’s claim construction to, as Sarepta and UWA urge, construe the term “base sequence” to require 100% complementarity across the *entire* claimed “antisense oligonucleotide.” No expert in this case—for either party—applied that construction in their reports. Accordingly, such a claim construction reversal on the eve of trial will require the parties to, at minimum, reopen expert discovery, serve new expert reports, and conduct new expert depositions. Given the fundamental unfairness and undue prejudice that would result from going to trial regarding patent invalidity for a patent with an entirely new claim construction that neither side’s expert contemplated or had an opportunity to address, NS would not be able to proceed to trial on the ’851 Patent as scheduled.

Insofar as the Court is inclined to reverse Judge Williams’s claim construction, NS requests that the Court refrain from issuing that ruling now and instead permit supplemental claim construction briefing and hold a new claim construction hearing so that the parties can be fully heard regarding this claim construction issue. Then, after the Court provides a new construction, the parties could proceed to reopen expert discovery regarding the invalidity of the ’851 Patent.

V. Other Claims and Defenses

Because the claim construction issues described herein do not impact the NS Patents at issue in Sarepta/UWA’s counterclaim for declaratory judgment of invalidity, NS respectfully requests that trial proceed as scheduled next week on the NS Patents and on Nippon Shinyaku’s breach of contract claim regardless of the Court’s determinations regarding

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claim construction of the '851 Patent. A trial regarding the '851 Patent can then commence at a date as soon as practicable after completing a supplemental claim construction hearing and expert discovery regarding the Court's new construction. To delay trial on the NS Patents over a wholly unrelated claim construction issue just days before the trial is scheduled to start will result in significant prejudice to NS and a waste of Court and party resources. The parties are ready to proceed to trial regarding the NS Patents, having invested significant time and resources into preparing for this trial, including bringing NS's fact witnesses and in-house counsel to Wilmington from Japan for the trial scheduled for next week. NS also recognizes the significant resources the Court has expended in addressing numerous motions and pretrial issues that pertain exclusively to the NS Patents. Simply put, trial can and should proceed now regarding the NS Patents no matter how the Court chooses to resolve the claim construction issues described herein.

* * *

NS is hopeful that trial can proceed on both the NS Patents and the '851 Patent. If this is not possible, it would be most efficient to proceed with trial on Monday as scheduled solely on the NS Patents, with the bench trial regarding Nippon Shinyaku's breach of contract claim to follow during jury deliberations.¹

Insofar as the Court is not amenable to proceeding with a jury trial on either both the '851 Patent and the NS Patents or solely on the NS Patents, Nippon Shinyaku respectfully requests that, at minimum, the Court hold the two-hour bench trial regarding Nippon Shinyaku's breach of contract claim early next week. Holding this brief bench trial early next week will make efficient use of Court and party resources especially given one of NS's witnesses for the breach of contract bench trial and interpreter are in Wilmington from Japan for the currently scheduled trial.

Respectfully submitted,

/s/ Amy M. Dudash

Amy M. Dudash (DE Bar No. 5741)

CC: Counsel of Record (Via CM/ECF)

¹ The parties have agreed to try Nippon Shinyaku's breach of contract claim to the Court via a two-hour bench trial, and this claim is not impacted by the claim construction issues discussed herein.